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10/809,140	03/25/2004	Hassan Chaouk	BioCure 260	7389

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EXAMINER

DANIELS, MATTHEW J

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/809,140
Filing Date: March 25, 2004
Appellant(s): CHAOUK ET AL.

MAILED
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Collen A. Beard
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 9 February 2006 appealing from the Office action mailed 9 September 2005.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6152943	SAWHNEY	11-2000
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5443454	TANABE	8-1995
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Callister, William D.. Materials Science and Engineering: An Introduction, John Wiley & Sons. 1991 , page 749, definition of "extrusion".

Merriam-Webster Collegiate Dictionary, Tenth Edition, Merriam-Webster, Inc., 1998, pages 414 and 458, definition of "extrude" and "form", respectively.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawhney (USPN 6152943) in view of Tanabe (USPN 5443454).

As to Claim 1, Sawhney teaches a method for forming a hydrogel comprising the steps: providing a delivery device having a gelation chamber (Fig. 3); providing a prepolymer composition that will form a hydrogel when brought into contact with a gelation initiator (2:64-3:6); contacting the prepolymer with the gelation initiator in the gelation chamber so that it forms a hydrogel in the gelation chamber (10:1-24); and extruding the hydrogel from the delivery device (Fig. 5A and 10:15-17). Sawhney appears to be silent to forming or extruding a string. However, this aspect of the invention would have been obvious over Tanabe, who teaches liquid substances introduced through lumen into a mixing chamber (Fig. 8A, Item 40c) and reactively solidifying to form a solid line or filament (13:44-54). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to combine the method of Tanabe with that of Sawhney in order to eliminate the dispersing and leakage of an embolic material out of the site of an aneurysm (Tanabe, 4:48-59). **As to Claim 2**, both Sawhney (Figs. 3 and 4) and Tanabe (Fig. 8A) teach a catheter delivery device. **As to Claim 3**, both Sawhney (Fig. 3, Items

49 and 49') and Tanabe (Figs. 8A, 8B, 9A) teach a multilumen catheter. **As to Claim 4**, both Sawhney (Fig. 3, Item 46) and Tanabe (Fig. 8A, Item 40c) teach a gelation chamber. **As to Claim 5**, Tanabe teaches a catheter that is coaxial having an inner catheter and an outer catheter and the method further comprising the step of sliding the inner catheter within the outer catheter to increase or decrease the length of the gelation chamber (14:16-18). **As to Claim 6**, Sawhney teaches a method wherein the prepolymer composition comprises at least two solutions that will form a hydrogel when combined in the gelation chamber (7:1-14 and 10:1-24). **As to Claim 7**, it would have been obvious or inherent in the method of Sawhney that hydrogel would have been extruded as prepolymer composition was moved to the gelation chamber (10:1-24). **As to Claim 8**, Sawhney teaches a hydrogel being formed in the gelation chamber, but is silent to the other claimed limitations. However, Tanabe teaches a delivery device that is a coaxial dual lumen catheter and the inner catheter is slidable within the outer catheter so that the degree of polymerization can be altered as the inner catheter is slid towards the distal end of the gelation chamber (14:16-18).

(10) Response to Argument

Appellant argues on Page 3 that Sawhney teaches away from the invention and away from the premature formation of the hydrogel, meaning formation of the hydrogel before it is at the body cavity or void. Appellant further argues that Sawhney clearly teaches to “deliver two or more fluent prepolymer solutions **without premature crosslinking**”

The Examiner respectfully disagrees with this characterization of Sawhney's method. Firstly, it must be noted that Sawhney's disclosure is directed to two different methods of

introducing polymerizing hydrogel material to achieve its objective. In the first embodiment, shown in Figures 1A to 2, Sawhney teaches that an actuator is depressed so that the solutions are delivered through outlet ports and mix outside of the catheter, forming a plug that occludes the desired area. This embodiment is also described in 9:49-54. In the second embodiment, described in 9:55-10:24, a mixing chamber (Fig. 3, Item 46) is provided in which two solutions that “crosslink spontaneously” (4:16-17) are mixed. The prepolymer solutions are injected via lumens (items 49 and 49’ in Fig. 3) “at a rate selected so that the prepolymer solutions begin crosslinking in chamber 46, with the resulting partially-formed gel being extruded through outlet ports 47” (Sawhney, 10:6-9). The second embodiment has been relied upon in the rejection.

The Appellant’s position is that Sawhney teaches away from a combination with Tanabe by teaching “without premature crosslinking”. The Examiner instead submits that Sawhney’s specific teaching of a “partially-formed” (10:8) gel in the embodiment relied upon appears to contradict the arguments presented. Additionally, Sawhney particularly teaches that one desires to avoid washout or dilution (10:8-12) of the hydrogel because of the risk of embolization elsewhere, and thus it would have been obvious or inherent that the extrudate would have existed in a state sufficiently formed (See “formed” in 10:8) that it would not have been dispersed by the vascular liquid. The references submitted by the Examiner on 29 November 2005, as a rebuttal to Appellant’s supplied definition, include dictionary definitions of “extrude” and “form” (See Merriam-Webster’s dictionary citation), and a textbook definition of “extrusion” (See Callister’s citation). The Examiner submits that Sawhney’s teachings of “partially-formed” (10:8) and “extruded” (10:8) each provide implicit teaching and suggestion that the hydrogel substance has shape or form when it leaves the mixing chamber, and is therefore not liquid. In this respect, it

should be noted that the claims were rejected under 35 USC 103(a), and not under 35 USC 102(b). The Examiner submits that the definitions provided, and Sawhney's teaching at 10:1-24, are believed to show that there is no teaching away from the combination with Tanabe.

Appellant argues on Page 4 that there is nothing to support the Examiner's assertion that the "partially formed" gel taught by Sawhney would have "obviously or inherently existed with some string-like characteristics". Appellant further argues that the primary definition for extrude should be used: "1: to force, press, or push out". Appellant further argues that a glob of partially formed gel pushed from a catheter could have a number of "shapes" or no shapes at all.

It should be noted that this appears to be an argument against the references individually, considering only Sawhney's disclosure. However, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. It should also be noted that Tanabe was relied upon for teaching of the string characteristics of the extruded filament. Tanabe clearly teaches a similar method, in which "two liquid substances are separately introduced through respective independent lumens to a common distal end thereof and are mixed in the distal end." (14:22-25). Tanabe further teaches that in the mixing lumen "these liquid substances react and begin to solidify" (emphasis added, 13:49-50) and are subsequently "extruded" (5:19-20) as a filament. Tanabe appears to teach the same partial formation which Sawhney also disclosed (10:8), but shows that this partial solidification produces a string-like shape. The rejection of the claims under 35 USC 103(a) does not rest on the inherency or obviousness of the shape or form of the substance which Sawhney extrudes. Tanabe provides a string, and motivation for doing so, namely to eliminate the dispersing and

leakage of an embolic material out of the site of an aneurysm (Tanabe, 4:48-59). The Examiner submits that this would have motivated one of ordinary skill to make the combination, and that all claim limitations are taught by the combination.

Appellant argues on Page 4 that Sawhney recognized this issue of dispersion of embolic material and provided a solution to the product, a partially polymerized product. Appellant further argues that one would not be motivated to look beyond Sawhney's method to Tanabe for a solution.

The Examiner respectfully disagrees, and instead submits that the methods of Sawhney and Tanabe are quite similar. Tanabe uses a particular apparatus which the ordinary artisan would have found more desirable than that of Sawhney because it allows adjustment of the length of the lumen, depending on the time required for the reaction of the two substances (14:16-18). The combination of Sawhney's material and method with Tanabe's apparatus and method is believed to be proper.

Additionally, the Appellant appears to argue that one would not be motivated to look beyond Sawhney's method because it provides a solution to the problem. However, the Examiner submits that the ordinary artisan would have been familiar with the references to Sawhney and Tanabe, and would have been motivated to make the combination for the reasons cited in the rejection, and to allow adjustment of the degree of polymerization of the material extruded from the catheter. The ordinary artisan would have been motivated to reduce the risk of migration of hydrogel material elsewhere in the body, and to make the combination with Tanabe, despite Sawhney's teaching of one solution to the problem.

Appellant further argues on Page 4 that the Examiner has improperly engaged in hindsight to modify the Sawhney reference to produce the claimed invention.

The Examiner submits that it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. In this case, the Examiner submits that both the hydrogel composition and apparatus were known from Sawhney and Tanabe, respectively. It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to combine the method of Tanabe with that of Sawhney in order to eliminate the dispersing and leakage of an embolic material out of the site of an aneurysm (Tanabe, 4:48-59).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Matthew J. Daniels



Conferees:

Michael P. Colaianni



Roy King

ROY KING



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